



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

GARDELLA *et al.*

Appl. No.: 10/549,592 (U.S. Nat'l Phase of
PCT/US2003/008261)

§ 371 Date: January 12, 2007

For: **Conformationally Constrained
Parathyroid Hormones With α -
Helix Stabilizers**

Confirmation No.: 2201

Art Unit: 1654

Examiner: *To Be Assigned*

Atty. Docket: 0609.5150000/TJS/PAC

Information Disclosure Statement under 37 C.F.R. § 1.97(b)

Mail Stop Amendment

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms, PTO/SB/08A and PTO/SB/08B are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of documents **FP1** and **NPL1-NPL36** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents, documents **US1** to **US5**, cited on the attached IDS Form, PTO/SB/08A, are not submitted.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may

not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

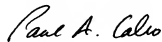
This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Paul A. Calvo
Attorney for Applicants
Registration No. 57,913

Date: 4/20/07

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

653089v1



Approved for use through 03/31/2007. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	10/549,592 (U.S. Nat'l Phase of PCT/US2003/008261)
§ 371 Date	January 12, 2007
First Named Inventor	GARDELLA, Thomas J.
Art Unit	1654
Examiner Name	<i>To Be Assigned</i>
Attorney Docket Number	0609.515000/TJS/PAC

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

652717v1

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation (symbol) (optional). ² See Kinda Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and/or by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending on the complexity of the case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



Equivalent of Form PTO/SB/08B (09-06)

Approved for use through 03/31/2007. OMB 0651-0031

U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

Complete if Known

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Application Number	10/549,592 (U.S. Nat'l Phase of PCT/US2003/008261)
§ 371 Date	January 12, 2007
First Named Inventor	GARDELLA, Thomas J.
Art Unit	1654
Examiner Name	To Be Assigned
Attorney Docket Number	0609.5150000/TJS/PAC

Sheet 1 of 4

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	NPL1	Barden, J.A. and Kemp, B.E., "NMR Solution Structure of Human Parathyroid Hormone(1-34)," <i>Biochemistry</i> 32:7126-7132, American Chemical Society (1993)	
	NPL2	Behar, V., et al., "Photoaffinity Cross-linking Identifies Differences in the Interactions of an Agonist and an Antagonist with the Parathyroid Hormone/Parathyroid Hormone-related Protein Receptor," <i>J. Biol. Chem.</i> 275:9-17, American Society for Biochemistry and Molecular Biology, Inc. (2000)	
	NPL3	Bergwitz, C., et al., "Full Activation of Chimeric Receptors by Hybrids between Parathyroid Hormone and Calcitonin," <i>J. Biol. Chem.</i> 271:26469-26472, The American Society for Biochemistry and Molecular Biology, Inc. (1996)	
	NPL4	Berridge, M.J., et al., "Changes in the levels of inositol phosphates after agonist-dependent hydrolysis of membrane phosphoinositides," <i>Biochem. J.</i> 212:473-482, The Biochemical Society (1983)	
	NPL5	Bowen, W.P. and Jerman, J.C., "Nonlinear regression using spreadsheets," <i>Trends Pharmacol Sci</i> 16:413-417, Elsevier, Science Ltd. (1995)	
	NPL6	Carter, P.H., et al., "Studies of the N-Terminal Region of a Parathyroid Hormone-Related Peptide(1-36) Analog: Receptor Subtype-Selective Agonists, Antagonists, and Photochemical Cross-Linking Agents," <i>Endocrinol.</i> 140:4972-4981, The Endocrine Society (1999)	
	NPL7	Chen, Z., et al., "Solution Structure of the Osteogenic 1-31 Fragment of Human Parathyroid Hormone," <i>Biochemistry</i> 39:12766-12777, American Chemical Society (2000)	
	NPL8	Chorev, M., et al., "Modifications of Position 12 in Parathyroid Hormone and Parathyroid Hormone Related Protein: Toward the Design of Highly Potent Antagonists," <i>Biochemistry</i> 29:1580-1586, American Chemical Society (1990)	
	NPL9	Dempster, D.W., et al., "Anabolic Actions of Parathyroid Hormone on Bone," <i>Endocrine Rev.</i> 14:690-709, The Endocrine Society (1993)	
	NPL10	Dempster, D.W., et al., "Erratum: Anabolic Actions of Parathyroid Hormone on Bone," <i>Endocrine Rev.</i> 15:261, The Endocrine Society (1994)	

652626v1

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



Equivalent of Form PTO/SB/08B (09-06)

Approved for use through 03/31/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Project of 1995, no person is required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/549,592 (U.S. Nat'l Phase of PCT/US2003/008261)
				§ 371 Date	January 12, 2007
				First Named Inventor	GARDELLA, Thomas J.
				Art Unit	1654
				Examiner Name	To Be Assigned
Sheet	2	of	4	Attorney Docket Number	0609.5150000/TJS/PAC

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T ²
	NPL11	Fairwell, T., <i>et al.</i> , "Total Solid-Phase Synthesis, Purification, and Characterization of Human Parathyroid Hormone-(1-84)," <i>Biochemistry</i> 22:2691-2697, American Chemical Society (1983)	
	NPL12	Gronwald, W., <i>et al.</i> , "Structure of Recombinant Human Parathyroid Hormone in Solution Using Multidimensional NMR Spectroscopy," <i>Chem. Hoppe-Seyler</i> 377:175-186, Walter de Gruyter & Co. (1996)	
	NPL13	Goud, N.A., <i>et al.</i> , "Solid-Phase Synthesis and Biologic Activity of Human Parathyroid Hormone(1-84)," <i>J. Bone Min. Res.</i> 6:781-789, Mary Ann Liebert, Inc. (1991)	
	NPL14	Hoare, S.R.J., <i>et al.</i> , "Evaluating the Signal Transduction Mechanism of the Parathyroid Hormone 1 Receptor," <i>J. Biol. Chem.</i> 276:7741-7753, American Society for Biochemistry and Molecular Biology, Inc. (2001)	
	NPL15	Jüppner, H., <i>et al.</i> , "A G Protein-Linked Receptor for Parathyroid Hormone and Parathyroid Hormone-Related Peptide," <i>Science</i> 254:1024-1026, American Society for the Advancement of Science (1991)	
	NPL16	Kaul, R and Balram, P., "Stereochemical Control of Peptide Folding," <i>Bioorg. Med. Chem.</i> 7:105-117, Elsevier Science Ltd. (1999)	
	NPL17	Kronenberg, H.M., <i>et al.</i> , "Parathyroid Hormone: Biosynthesis, Secretion, Chemistry, and Action" in: <i>Handbook of Experimental Pharmacology</i> , Mundy, G.R., and Martin, T.J., eds., Springer-Verlag, Berlin, Germany, pp.507-567 (1993)	
	NPL18	Luck, M.D., <i>et al.</i> , "The (1-14) Fragment of Parathyroid Hormone (PTH) Activates Intact and Amino-Terminally Truncated PTH-1 Receptors," <i>Mol. Endocrinol.</i> 13:670-680, The Endocrine Society (1999)	
	NPL19	Marx, U.C., <i>et al.</i> , "Structure of Human Parathyroid Hormone 1-37 in Solution," <i>J. Biol. Chem.</i> 270:15194-15202, The American Society for Biochemistry and Molecular Biology, Inc. (1995)	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



Equivalent of Form PTO/SB/088 (09-06)
Approved for use through 03/31/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number	10/549,592 (U.S. Nat'l Phase of PCT/US2003/008261)
		§ 371 Date	January 12, 2007
		First Named Inventor	GARDELLA, Thomas J.
		Art Unit	1654
		Examiner Name	To Be Assigned
Sheet	3 of 4	Attorney Docket Number	0609.5150000/TJS/PAC

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T ²
	NPL20	Marx, U.C., <i>et al.</i> , "Structure-Activity Relation of NH ₂ -terminal Human Parathyroid Hormone Fragments," <i>J. Biol. Chem.</i> 273:4308-4316, American Society for Biochemistry and Molecular Biology, Inc. (1998)	
	NPL21	Marx, U.C., <i>et al.</i> , "Solution Structures of Human Parathyroid Hormone Fragments hPTH(1-34) and hPTH(1-39) and Bovine Parathyroid Hormone Fragment bPTH(1-37)," <i>Biochem. Biophys. Res. Commun.</i> 267:213-220, Academic Press (2000)	
	NPL22	Neer, R.M., <i>et al.</i> , "Effect of Parathyroid Hormone (1-34) On Fractures and Bone Mineral Density in Postmenopausal Women with Osteoporosis," <i>N. Eng. J. Med.</i> 344:1434-1441, Massachusetts Medical Society (2001)	
	NPL23	Pellegrini, M., <i>et al.</i> , "Binding Domain of Human Parathyroid Hormone Receptor: From Conformation to Function," <i>Biochemistry</i> 37:12737-12743, American Chemical Society (1998)	
	NPL24	Robinson J.R. ed., "Methods to Achieve Controlled Drug Delivery," in: <i>Sustained and Controlled Release Drug Delivery Systems</i> , Marcel Dekker, New York, NY, pp 557-593 (1978)	
	NPL25	Shen, V., <i>et al.</i> , "Effects of Combined and Separate Intermittent Administration of Low-Dose Human Parathyroid Hormone Fragment (1-34) and 17β-Estradiol on Bone Histomorphometry in Ovariectomized Rats with Established Osteopenia," <i>Calcif. Tissue Int.</i> 50:214-220, Springer-Verlag Inc. (1992)	
	NPL26	Shimizu, M., <i>et al.</i> , "Autoactivation of Type-1 Parathyroid Hormone Receptors Containing a Tethered Ligand," <i>J. Biol. Chem.</i> 275:19456-19460, The American Society for Biochemistry and Molecular Biology, Inc. (2000)	
	NPL27	Shimizu, M., <i>et al.</i> , "Minimization of Parathyroid Hormone," <i>J. Biol. Chem.</i> 275:21836-21843, The American Society for Biochemistry and Molecular Biology, Inc. (2000)	
	NPL28	Shimizu, M., <i>et al.</i> , "Enhanced Activity in Parathyroid Hormone-(1-14) and -(1-11): Novel Peptides for Probing Ligand-Receptor Interactions," <i>Endocrinol.</i> 142:3068-3074, Endocrine Society (2001)	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



Equivalent of Form PTO/SB/08B (09-06)

Approved for use through 03/31/2007. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
 Required to respond to a collection of information unless it contains a valid OMB control number.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number	10/549,592 (U.S. Nat'l Phase of PCT/US2003/008261)
		§ 371 Date	January 12, 2007
		First Named Inventor	GARDELLA, Thomas J.
		Art Unit	1654
		Examiner Name	To Be Assigned
Sheet	4	of	4
		Attorney Docket Number	0609.5150000/TJS/PAC

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T ²
	NPL29	Shimizu, N., <i>et al.</i> , "Parathyroid Hormone (PTH)-(1-14) and -(1-11) Analogs Conformationally Constrained by α -Aminobutyric Acid Mediate Full Agonist Responses via the Juxtamembrane Region of the PTH-1 Receptor," <i>J. Biol. Chem.</i> 276:49003-49012, The American Society for Biochemistry and Molecular Biology, Inc. (2001)	
	NPL30	Slovik, D.M., <i>et al.</i> , "Restoration of Spinal Bone in Osteoporotic Men by Treatment with Human Parathyroid Hormone (1-34) and 1,25-Dihydroxyvitamin D," <i>J. Bone Min. Res.</i> 1:377-381, Mary Ann Liebert, Inc. (1986)	
	NPL31	Takasu, H., <i>et al.</i> , "Amino Terminal Modifications of Human Parathyroid Hormone (PTH) Selectively Alter Phospholipase C Signaling via the Type 1 PTH Receptor: Implications for Design for Signal-Specific PTH Ligands," <i>Biochemistry</i> 38:13453-13460, American Chemical Society (1999)	
	NPL32	Takasu, H., <i>et al.</i> , "Dual Signaling and Ligand Selectivity of the Human PTH/PTHrP Receptor," <i>J. Bone Min. Res.</i> 14:11-20, Blackwell Science, Inc. (1999)	
	NPL33	Tregear, G.W., <i>et al.</i> , "Bovine Parathyroid Hormone: Minimum Chain Length of Synthetic Peptide Required for Biological Activity," <i>Endocrinol.</i> 93:1349-1353, The Endocrine Society (1973)	
	NPL34	Whitefield, J.F., <i>et al.</i> , "Restoration of Severely Depleted Femoral Trabecular Bone in Ovariectomized Rats by Parathyroid Hormone-(1-34)," <i>Calcif. Tissue Int.</i> 56:227-231, Springer-Verlag Inc. (1995)	
	NPL35	Whitfield, J.F., <i>et al.</i> , "Comparison of the Ability of Recombinant Human Parathyroid Hormone, rhPTH-(1-84), and hPTH-(1-31)NH ₂ Stimulate Femoral Trabecular Bone Growth in Ovariectomized Rats," <i>Calcif. Tissue Int.</i> 60:26-29, Springer-Verlag Inc. (1997)	
	NPL36	Wold, F., "Posttranslational Protein Modifications: Perspectives and Prospects," in <i>Posttranslational Covalent Modifications of Proteins</i> , B.C. Johnson, eds., Academic Press, Inc., New York, pp. 1-12 (1983)	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.